MIADERMA

Medical Device €

Anti Itch Cream

- Treats chronic dry, irritated and itchy skin
- · Free of perfume, coloring agents and preserving, parabens, mineral oils
- Free of cortisones or other hormones

General recommendations:

Carefully read the instructions for use before taking Anti-itch cream, even if you have used this medical device before. The information may have been amended according to new research and findings in the time since your last opened package. Keep this information in case you need to consult it again.

How does Anti-itch cream work?

Anti-itch cream is a topical medical device for management of chronic dry skin (xerosis) and relieving symptoms of atopic dermatitis. Atopic dermatitis is a chronic, relapsing skin disease characterized by xerosis (dry skin) and pruritus (itching). Anti-itch cream is composed of a combination of key ingredients that are categorized as emollients, humectants and occlusives, which work synergistically to enhance hydration and barrier function.

Anti-itch cream contains the moisturizing complex with emollient, humectant and protectant properties that contribute to skin barrier repair and improved barrier function and offer physical protection from irritants and allergens. The product contains four active ingredients: glycerin, olus (vegetable) oil, dimethicone, ceramide NP. Olus oil (functional alternative for petrolatum) and Dimethicone, as occlusives, work by forming a hydrophobic layer on the surface of the skin providing an exogenous barrier to water loss. Glycerin increase the water content of the skin by enhancing water absorption from the dermis into the epidermis. Ceramides form lipids to retain moisture and restore suppleness to the skin.

Ingredients:

Aqua, Caprylic/Capric Triglyceride, Dicaprylyl Carbonate, Polyglyceryl-2 Dipolyhydroxystearate, Glycerine, Behenyl Alcohol, Olus Oil, Sodium Polyacrylate, Pentaerythrityl Distearate, Panthenol, Phenethyl Alcohol, Pentylene Glycol, Caprylyl Glycol, Butylene Glycol, Coco Caprylate, Squalane, Lauryl Glucoside, Sodium Lauryl Glucose Carboxylate, Allantoin. Hydrogenated Phosphatidylcholine, Butyrospermum Parkii Butter, Tocopheryl acetate, Hydroxyphenyl Propamidobenzoic Acid. Sodium Hvaluronate, Ceramide NP, Ascorbyl Palmitate,

Directions:

Anti-itch cream is for topical use for adults and children of all ages. The product should be applied to affected areas two-three times a day, for not more than 30 days. Anti-itch cream is indicated for use as monotherapy or adjunctive therapy in the management of dry or itchy skin. It may also be used in combination with standard topical or systemic therapy, including topical corticosteroids since it has no known drug interactions.

Use during pregnancy and /or breastfeeding:

Anti-itch cream is not recommended during pregnancy and / or breastfeeding.

Possible side effects:

Anti-itch cream is well tolerated and has no known side effects. There may occur a stinging sensation after application of the cream.



- · Keep out of reach of young children;
- · Do not use in case of hypersensitivity to one of the ingredients.



Method of storage: Room temperature (5-25°C) in a dry, dark place, in the original container and out of reach of young children.

Medical device: Anti-itch cream is a Class I medical device conform the medical device directive 93/42/EEC.



Expiry date: For the expiry date please see the packaging. Do not use Anti-itch cream after this date.

Date of most recent revision of these instructions for use: October 2019 • 080062BY-V1.0



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If you would like further information about this product, please contact: Miaderma Regulatory Services Samuel Ryder House, Barling Way Nuneaton, Warwickshire, CV10 7RH United Kingdom

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